Zemun, Baranjska 15, Yugoslavia P. O. Box 46; Tel: 607-666, 608-504

Date: 15th October 1978

Department of Physiology and Radiobiology, Institute for the Application of Nuclear Energy in Agriculture, Veterinary Medicine and Forestry, Z e m u n

in collaboration with

Laboratory for Molecular Biology and Endocrinology, Institute for Nuclear Sciences "Boris Kidrić", Vinča

and

Department of Forensic Veterinary Medicine, Faculty of Veterinary Medicine University of Belgrade

REPORT

ON AN EXAMINATION OF AGROSTEMIN PREPARATION FOR TOXICITY

October, 1978

Zemun, Baranjska 15, Yugoslavia P. O. Box 46; Tel: 607-666, 608-504

Page	2
I usc	_

On the basis of the results of our examinations, the producer's records and literature data the results of an examination, including evaluation and an opinion on the toxic properties of Agrostemin preparation are given as follows.

<u>Name of preparation:</u> AGROSTEMIN (Patent Document. No. 32 749, Federal Commission for Patents, SFR Yugoslavia).

<u>Composition of preparation:</u> Agrostemin is the commercial term for a preparation which consists of corn cockle powder (Agrostemma githago) (50%) and other plants (cultivated weeds).

The preparation is produced in the form of a yellow-grayish powder, poorly soluble in water.

Chemical composition:

Allantoin, %	25,90
<i>Tryptophan,</i> %	
Folic acid, %	
<i>Glycine</i> , %	
Alanine, %	
Aspartic acid, %	
Threonine, %	
<i>Serine</i> , %	
Glutamic acid, %	
Proline, %	
Valine, %	0,24
Isoleucine, %	
Leucine, %	0,35
Phenylalanine, %	
Alanthoic acid, %	33,00
Orcialanine, %	2,50
Adenine, %	5,00

<u>Purpose:</u> Agrostemin is used to stimulate the growth and development of plants of the alanthoic species in order to improve the quality and quantity of the yield.

^{*)} According to the Report No. 15496 of August 23, 1976 from CIENTEC - FUNDACAO DE CIENCIA E TECNOLOGIA, Porto Alegre, Brazil.

^{**)} According to Patent Document No. 32 749, Federal Commission for Patents, SFR Yugoslavia

Zemun, Baranjska 15, Yugoslavia P. O. Box 46; Tel: 607-666, 608-504

<u>Producer:</u> Hunting-Forestry Husbandry "Jelen", Department "Bioprodukt", Kneza Miloša 55, 11000 Beograd, Yugoslavia.

Object of the examination of toxicological properties: The prescribed examinations in experimental animals and in tissue culture could not be performed due to the fact that Agrostemin is poorly soluble in water. Therefore, a water soluble fraction was used for lyophilized and this preparation examinations. In this way, sterile and easy water soluble preparation was obtained. The amount of the preparation is expressed in gram-initial weight of Agrostemin preparation.

The preparation was dissolved in sterile redistilled water immediately before use. The pH of the solution in all examinations was 6,9.

In some tests, as for instance: examination of accumulation in the food chain system and environmental degradation Agrostemin was mixed with talc as a carrier. In examination of toxicity in fish and snails Agrostemin without carrier was applied.

Zemun, Baranjska 15, Yugoslavia P. O. Box 46; Tel: 607-666, 608-504

Page ____4__

CONTENTS

FOXICOLOGICAL PROPERTIES	5
ACUTE TOXICITY	
Determination of the toxicity of the preparation applied orally to rats. Determination of the toxicity of the preparation applied orally to mice. Determination of the toxicity of preparation to rabbit skin. Determination of the toxicity of the preparation after a single 1 hour inhalation by	5 6
CHRONIC TOXICITY	6
Examination of the stimulative effect of the preparation on rabbit's eyes	7 7
Examination of accumulation in the food chain system (toxic affect of the degrade product).	ed 8
Determination of allantoin in lucerne, soy-bean and sunflower treated with Agrostoby chemical tests	
EXAMINATION OF THE PREPARATION FOR MUTAGENICITY/CANCEROGENITY	10
EXAMINATION OF THE PREPARATION FOR TERATOGENICITY	
CONSIDERATION OP THE RESULTS AND LITERATURE DATA	
Metabolism of the active principle Degradation within the environment Persistence in the environment	11
Toxicity of the degraded product	12
CONCLUSION AND OPINION	13
_ITERATURE	14

Zemun, Baranjska 15, Yugoslavia P. O. Box 46; Tel: 607-666, 608-504

Page 15	Page	13
---------	------	----

CONCLUSION AND OPINION

On the basis of the results obtained, the documentation of the producer and examined scientific and professional literature, it can be concluded that the preparation obtained by water extraction of Agrostemin and lyophilization, in high concentrations has no toxic effect in the examined animals, cells in culture and the environment.

It is therefore considered that Agrostemin is not harmful to human and animal health; the prescribed measures of hygienic and technical protection are followed during its production and application.

In our opinion, the preparation can be used for the intended purposes, in the doses prescribed by the producer, amounting to 1,0 gr/ha soil, i.e. 0,1 mg/kg (without carrier).

Chief Investigator,

LEACE USON

Čedomir Rusov, Dr. Vet. Med., Senior Scientific Officer